FEB - 2 2009

SECTION 5: 510(k) SUMMARY (21 CFR §807.92(c))

Submitter: Avinger, Inc.
400 Chesapeake Dr
Redwood City, CA 94063
Phone: 650.216.7400
Fax: 650.216.7406

Contact: Himanshu Patel
President & CEO

Date Summary Prepared: November 7, 2008

Device Trade Name: Wildcat 7F Guidewire Support Catheter

Common Name: Guidewire Support Catheter

Classification Name: Percutaneous Catheter (21 CFR §870.1250)

Product Code: DQY

Equivalent Device(s):

- Asahi Tornus Support Catheter (K060745) manufactured by Asahi Intecc Co., Ltd.
- GOPHER Support Catheter (K070372) manufactured by Vascular Solutions, Inc.

Device Description:
The Avinger Wildcat 7F Guidewire Support Catheter (Wildcat 7F) is a sterile, single-use, disposable catheter designed to support steerable guidewires in accessing discrete regions within the peripheral vasculature.

The Avinger Wildcat 7F catheter consists of a distal tip, catheter shaft and proximal handle that allows for device manipulation and a means for flushing the catheter lumen. The catheter has a working length of 135 cm and is compatible with 0.035" guidewires. Two key elements of the device define the treatment modality – the distal tip and bilateral wedges. Both elements are visible through fluoroscopy and support steerable guidewires in accessing the discrete region of interest within the peripheral vasculature.

Subsequent to conventional guidewire placement, athetercomy devices, PTCA catheters and/or stents may be used to provide therapeutic benefit. The Wildcat 7F catheter in and of itself does not provide any therapeutic benefit beyond simple facilitation of guidewire support.

Intended Use:
The Wildcat 7F Guidewire Support Catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline/contrast.

Nonclinical Performance Data:
Design analysis data confirm that the Wildcat device performs according to the stated intended use. Device evaluation consisted of laboratory testing specified in ISO10555-1 Sterile, single-use intravascular catheters – Part I – General Requirements (1995-06-15) and included tensile, torque strength, coating integrity and device compatibility. Biocompatibility testing was conducted according to ISO 10993 "Biological Evaluation of Medical Devices". All data fell well within pre-determined product specifications and external standard requirements. In addition, device performance was successfully evaluated in a porcine animal model.

Statement of Equivalence:
The Avinger Wildcat Guidewire Support Catheter is substantially equivalent to the Asahi Tornus and GOPHER support catheters. Both the subject device and predicate devices are intended for use with steerable guidewires to access discrete regions of the peripheral vasculature. Additionally, both the subject and predicate devices may be used to facilitate placement and exchange of guidewires and/or other interventional devices. Like the GOPHER catheter, the Avinger device may also be used to infuse/deliver saline or contrast. However, unlike the GOPHER device, the Avinger catheter is indicated for use in the peripheral vasculature only.

The subject and predicate devices are made of similar materials and function according to similar operating principles. Both Gopher and Wildcat devices contain a threaded distal tip which allows for vascular access and guidewire exchange. Additionally, both the subject and predicate devices are compatible with standard guidewires to facilitate peripheral interventional procedures. All devices are designed to support the guidewire while accessing discrete regions of the vascular anatomy.

Summary:
Based upon the product technical information, intended use, performance and biocompatibility information provided in this pre-market notification, the Avinger Wildcat Catheter has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

Avinger, Inc.
c/o Mr. Himanshu Patel
President and CEO
400 Chesapeake Drive
Redwood City, CA 94063

Re: K083313
Wildcat 7F Guidewire Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 7, 2008
Received: November 10, 2008

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number if known: ~~TBD~~ K083313

Device Name: Wildcat 7F Guidewire Support Catheter

Indications for Use:

The Wildcat 7F Guidewire Support Catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline/contrast.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083313